| 1 | UNITED STATES DISTRICT COURT |
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| 2 | FOR THE DISTRICT OF MASSACHUSETTS |
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| 4 | THE UNITED STATES OF AMERICA) |
| 5 | Plaintiff,) Civil Action |
| 6 | v. No. 1:20-cv-11401-PBS |
| 7 |) Pages 1 to 25 Regeneron Pharmaceuticals,) Inc. et al,) |
| 8 | |
| 9 | Defendant.) |
| 10 | |
| 11 | |
| 12 | BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE |
| 13 | |
| 14 | MOTION HEARING |
| 15 | |
| 16 | May 22, 2024 11:00 a.m. |
| 17 | |
| 18 | John J. Moakley United States Courthouse Courtroom No. 19 |
| 19 | One Courthouse Way Boston, Massachusetts 02210 |
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| 22 | |
| 23 | Jessica M. Leonard, CSR, FCRR Official Court Reporter |
| 24 | John J. Moakley United States Courthouse One Courthouse Way |
| 25 | Boston, Massachusetts 02210 JessicaMichaelLeonard@gmail.com |
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- 1 PROCEEDINGS
- THE CLERK: Court calls civil action 1:20-cv-11401,
- 3 The United States of America v. Regeneron Pharmaceuticals, Inc.
- 4 et al. Could counsel please identify themselves?
- 5 MS. SEOL: Good morning, Your Honor. Diane Seol for
- 6 the United States and I'm joined by my colleagues, assistant US
- 7 Attorneys Lindsey Ross and Abe George as well as trial
- 8 attorneys Doug Rosenthal and Sam Lehman.
- 9 MR. BROOKS: Good morning, Your Honor. Ross Brooks of
- 10 Brooks LLC, I'm here for the relators.
- MR. KATZENSTEIN: Good morning, Your Honor. Jeff
- 12 Katzenstein, local counsel for the relators.
- 13 MS. PHILLIPS: Good morning, Your Honor. My name is
- 14 Lareena Phillips. I'm with the North Carolina Medicaid
- 15 Investigations Division and we've also got attorneys from the
- 16 intervening states of Colorado. We've got Hannah Perng,
- 17 Georgia; James Champlin; Michigan, Deshawn Madha; Texas, Lynne
- 18 Citrin, and Washington, Ferdinand Lugo-Ortiz. And Ian Marinoff
- 19 has entered an appearance for this case as we work pro hac vice
- 20 admissions.
- MR. NOONAN: Good morning, Your Honor. Greg Noonan of
- 22 Hogan Lovells on behalf of Regeneron with my colleagues Gejaa
- 23 Gobena and Mitch Lazris.
- 24 THE COURT: So I want everyone to turn off their video
- 25 unless they're speaking today. Who are the primary people

- 1 working? Who's representing the Government?
- MS. SEOL: I am, Your Honor.
- 3 THE COURT: Who's representing the defendants?
- 4 MR. NOONAN: I am, Your Honor.
- 5 THE COURT: Is there anyone here representing the
- 6 states?
- 7 MS. PHILLIPS: I will speak on behalf of the states
- 8 today, Your Honor.
- 9 THE COURT: You didn't file anything, right?
- MS. PHILLIPS: We have not, no. We're working through
- 11 pro hac vice admissions. We've only filed the notice of the
- 12 intent to -- the intervention.
- 13 THE COURT: All right. So I'm going to ask you to
- 14 turn off your video if you're not speaking today. This is a
- 15 highly unusual situation. I have never, in 30 years, had
- 16 people contesting confidentiality in such an intense way at the
- 17 initial filing of a complaint. And I know this is a
- 18 whistleblower claim so it's quite an old case, but it's new for
- 19 me. So I am trying to understand the dynamic here.
- 20 And let me start with the Government here. As you
- 21 know, I've handled many, many whistleblowers, including I was
- 22 the presiding judge in the multidistrict litigation AWP case,
- 23 so I'm familiar with these kinds of drug-pricing issues. I
- 24 have never seen a thousand pages attached to a complaint.
- 25 Never. I've seen contracts. Occasionally I've seen policies.

- 1 I have never seen -- your complaint reads like a motion for
- 2 summary judgment. And so I'm trying to understand it,
- 3 actually. And just so I'm not loading just on you, from the
- 4 defense point of view, I started looking at some of this stuff,
- 5 I didn't agree it was confidential. I just looked at the very
- 6 first thing, the very first red box, doesn't look confidential
- 7 to me.
- And some of these cases are 13 years old and I don't
- 9 buy the statement of, Oh, that one liner from your affiant
- 10 saying how they stay roughly the same. I don't believe it in
- 11 all the different subparts. So I'm just trying to understand
- 12 this case, and maybe I can start with you, with the Government.
- 13 What would be wrong with just, essentially, your allegations --
- 14 it's a very thorough complaint -- just citing the exhibit
- 15 you're referring to without incorporating it into the
- 16 complaint. Because under the rules -- I'm sure you looked at
- 17 the rules, the Rules of Civil Procedure -- any exhibit attached
- 18 is considered fully part of the complaint which, by definition,
- 19 would mean this is not a short and plain statement of a case.
- 20 So is there a -- can I say a fallback position or a
- 21 Plan "B" from the Government to just stick in that -- either
- just reference the exhibit, and if we need it for the motion to
- dismiss, I can do it, or potentially just sticking in the part
- 24 just essential to the complaint. In other words, editing the
- 25 document, for want of a better word.

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1
              MS. SEOL:
                         I understand.
 2
              (The court reporter interrupts.)
 3
              THE COURT: I have trouble hearing you, too.
 4
              MS. SEOL: I'm sorry about that. Is my volume okay?
 5
              THE COURT: Right now I can hear you, yes.
                         I think what we would say is it's not -- in
 6
              MS. SEOL:
 7
     our practice in this district, we have attached exhibits to
     complaints, including in a prior litigation against this very
 8
 9
     defendant, Regeneron, in a case that's pending before Judge
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     Ziegler. And as we did explain to Regeneron's counsel in the
11
     lead-up to this hearing, part of the reason why we did this is
12
    because we felt that the information that we were citing was
13
    most effective in this very complicated litigation, as Your
14
     Honor alluded to, when seen in the whole context of the
15
     original document.
16
              THE COURT: I'm not going to allow you to file full
17
     documents. I don't know what was in Judge Saylor's case.
18
     doubt it was a thousand pages. I just doubt it. So I'm not
19
     saying I'm not going to allow you to attach anything, I mean,
20
     you have a right to attach an exhibit, I'm not going to allow
21
     you to attach a thousand pages. You yourself would admit that
     not all of it -- if you think some of it's critical, that may
22
23
     be, but you're going to have to do some editing, so I'm not
24
     sitting there wondering whether or not the exact price of an
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insurance policy is relevant to a credit card claim. I mean,

25

- 1 that's -- I don't need that.
- 2 But there are some parts that you say in your memos
- 3 that are critical to your claim to understanding it, so I need
- 4 you to do the original laboring work of just editing to the
- 5 point where, in your view, it's a critical statement, and then
- 6 I will get to the issue of confidentiality. Now, a short
- 7 cut -- and I want to see if this is something that might be
- 8 acceptable. Let me be very clear: Neither I, nor will I ask a
- 9 magistrate judge, to review a thousand pages at the beginning
- 10 of a case and figure out what's confidential and what isn't. I
- 11 started going through it. We had trouble even docketing it.
- 12 So I'm not doing it.
- So I'm trying to create a more efficient way of
- 14 handing this. And one part -- and I'm going to ask defense
- 15 about this -- would be simply referencing the exhibit. And
- 16 then if, in the motion to dismiss -- which is likely to be
- 17 filed, if day follows night and night follows day -- you need
- 18 that, anything in there you could reference it. That would be
- one way of handling it, because in the exhibit that's
- 20 referenced, I think I can use without actually attaching.
- Mr. Noonan, would you agree with that?
- MR. NOONAN: Yes, Your Honor. We would agree with
- 23 that. We're also willing to work with the Government should
- 24 they want to simply narrow the size and scope of the exhibits.
- 25 We'd be more than happy to work with them on that and let them

- 1 do that for confidentiality.
- THE COURT: So if, instead of just attaching
- 3 everything, we simply let you cite the exhibit so it's not
- 4 immediately part of the public docket, that would be one -- I'm
- 5 not making you answer right now, by the way. You may want to
- 6 confer with counsel.
- Road one, you reference the exhibit maybe by Bates
- 8 stamp number or just by Exhibit 1, 2, 3. You don't attach it
- 9 to the complaint, and you can use it fully for purposes of an
- 10 Iqbal/Twombly motion. Or a 9(b). That's one route.
- 11 Second route is you and your team -- either in the US
- 12 Attorney's Office locally or you've got the Department of
- 13 Justice behind you -- go through it and decide what is
- 14 essential to your claim rather than everything under the sun
- and just edit it down and then I can focus more narrowly on
- 16 what's confidential instead of getting into the weeds of
- 17 inventory levels and supply chain and insurance policies and
- 18 the like. So that's path two is edit it down.
- And I guess part three would be just essentially
- 20 coming up with an alternative, if you insist on it. I've got
- 21 all these rules behind me. Essentially, we could go through a
- 22 motion to strike as superfluous. We could go through the Rule
- 23 8, which is short and plain statement of the facts. But I'm
- 24 not sure we have to do that right now. It's just so early in
- 25 the case. So that's one thing.

- 1 So let me just stop there, and I don't expect you to
- 2 necessarily answer it right now, but I for sure am not going
- 3 through all these objections for things that aren't important
- 4 to you. Some of it you said are important to you, and I might
- 5 even agree with you, but then -- but then if he's going to
- 6 agree that all the exhibits can be used in Iqbal/Twombly
- 7 motions, I don't see why I need to do that right now.
- 8 MS. SEOL: We certainly understand the Court's
- 9 position. That's something I'm happy to discuss with my
- 10 colleagues and we can work with Regeneron.
- 11 THE COURT: Perfect. Now, let me get to the defense
- 12 for a minute. The very first thing that's red boxed doesn't
- 13 look confidential to me. That the thing that Besse Medical
- 14 sent to me was 13 years old. In AWP, we went on a presumptive
- 15 level of five years. Now, that was a long time ago and it's a
- 16 different industry and different players and I understand that,
- 17 it's not definitive, it's just presumptive. I'm not going to
- 18 presume that something that's 13 years old -- pricing
- 19 information -- is still competitive. And there's 13-year-old
- 20 discussions of inventory or insurance policies -- if they're
- 21 important, they may not be -- are stale.
- So I'm trying to figure out what to do with that,
- 23 whether I should adopt a presumptive policy. Would that be
- 24 helpful to you?
- MR. NOONAN: Well, Your Honor, I certainly hear what

- 1 you're saying, but age -- I don't think age alone should be
- 2 determinative, and I think an example of that would be -- I
- 3 hear you when you're talking about, say, what level of
- 4 inventory to keep in 2013. But, for example, the reasonable
- 5 assumptions document, which is Exhibit 43, is an eight-year-old
- 6 document, but that document is replete with confidential
- 7 information that is as relevant today as it was eight years
- 8 ago. So it would be --
- 9 THE COURT: It may be. But that doesn't mean that I'm
- 10 going to -- that's what we did in AWP. It wasn't a definitive
- 11 rule, it's just, for you to claim a 13-year-old document puts
- 12 you at a competitive disadvantage, given everything that's
- 13 happened, not to mention inflation or changes with COVID or
- 14 changes in supply chain, I don't believe it. I would have to
- 15 know a whole lot more than just one line in an affidavit which
- 16 wasn't even definitive, it was just a catch-all, if you will.
- 17 So that's one part of it. And part of it, too, is --
- 18 let me just see if I can show you. Here's this big mega
- 19 binder, which I'm not going through one by one. Exhibit 1, the
- 20 first thing that's red bracketed is -- I think it's a 2018
- 21 document, which now puts it as six years old says, "We are
- 22 investigating new indications in delivery technologies to
- 23 address significant unmet needs in the market including
- 24 extending dosing intervals, new disease states, and dose
- 25 preparation and administration." That's sort of an

- 1 aspirational boilerplate statement and it looks like a
- 2 PowerPoint. That's not confidential. I would rule it wasn't
- 3 confidential. All the thing like dosing interviews, et cetera,
- 4 that's common to the industry so -- so I don't want to do that.
- 5 MR. NOONAN: Understood, Your Honor. I completely
- 6 hear where you're coming from and we, too, wish to avoid this
- 7 exact circumstance. I have not seen anywhere near as many
- 8 cases as you have but I, too, have never seen a case which
- 9 1,500 pages are attached to the complaint. Ms. Seol is
- 10 discussing about the Regeneron Charitable Foundation case in
- 11 front of Judge Saylor. I believe that was approximately 200
- 12 pages of document. The Teva case in front of Judge Gorton, the
- 13 Government attached 300 pages of documents. That sounds like a
- lot to me in and of itself, but it's not a 1500.
- 15 What we tried to do is we tried to leave alone
- 16 anything we thought, based on the reading of the complaint, was
- 17 a core allegation, which is the payment and credit card fees
- 18 and how such payment should be treated for price-supporting
- 19 purposes. I absolutely hear what the Court is saying about
- 20 age, and I will, as an explanation if not an excuse, say that
- 21 we, too, struggled on a relatively short timeline to get
- through 1,500 pages of exhibits and figure out what was and not
- 23 confidential.
- I'm positive that, like most counsel for companies
- 25 that consider all their information confidential, we may have

- 1 erred in some places with too heavy a hand and we'd be more
- 2 than happy either to go with how the Court has proposed and
- 3 simply refer to the exhibits, or to work with the Government on
- 4 a reduced set of exhibits with reduced pages and take a more
- 5 streamlined approach to what is or is not confidential.
- 6 THE COURT: I think what should happen is the
- 7 Government -- they didn't know what I was going to do today.
- 8 It's not new to you all, but it's really new to me. I mean, I
- 9 would get the periodic typical six-month extension kinds of
- 10 things, but I didn't really dive into the case at all. I
- 11 didn't pay attention to it until recently. But I'm focused.
- So from the Government's point of view, would two
- 13 weeks be enough time to let me know what approach you want to
- 14 take?
- MS. SEOL: Yes, Your Honor.
- THE COURT: Okay. So that puts us by, let's say,
- 17 June -- well, the seventh? By June 7 you can figure out --
- 18 does that make sense -- whether or not you want to, a,
- 19 essentially agree that all exhibits referred to can be used in
- 20 any Iqbal/Twombly motion; b, whether or not you want to just go
- 21 through it exhibit by exhibit and carve off the parts that you
- 22 view as essential to your case and then I can do -- winnow down
- 23 confidentiality analysis. And I think those are my only two
- 24 options short of a, we're not budging and then I'm going to
- 25 start dealing with rules that I haven't looked at in a long

- 1 time, which is on my own I can strike the things as I read it.
- 2 It also says, "adoption by reference exhibits." That's rule
- 3 10(c), and there's short and plain statement of a facts, Rule
- 4 8, and then there's motion to strike -- which the Court can do
- 5 on its own -- redundant immaterial information. It says here
- 6 "impertinent or scandalous." There's nothing like that. But
- 7 either redundant or immaterial.
- 8 So I don't want to go through them. I want you to
- 9 essentially sort of winnow this down in a way it becomes
- 10 manageable, frankly, for you as well as for me and for Defense.
- 11 Just sort of get it down to the essentials. The second thing,
- 12 you've got to go through this. If they decide to go on the
- 13 essential pieces of it --
- 14 MR. NOONAN: We will reassess, Your Honor, absolutely.
- THE COURT: I don't know who went through these,
- 16 whether it was the company or whether it was a paralegal or
- 17 whatever, but I think you and other people who've got
- 18 experience maybe need to go through this as to what's really
- 19 viable or not. Because one way or another, we're going to have
- 20 to do that with your inevitable Iqbal/Twombly motion.
- MR. NOONAN: Yes, Your Honor, understood.
- 22 THE COURT: Let me ask you this. This case has been
- 23 pending for so long. This is one of the ones I rant and rail
- 24 about because they take forever to get through. It's now a
- 25 four-year-old case, maybe five years. I don't know the legal

- 1 issues at all yet, other than I am highly trained in AWP so I
- 2 understand the notion of the spread pretty well. But let me
- 3 just say this: I don't want a briefing schedule that goes on
- 4 for another six months and then it takes me three to six months
- 5 to write it. That already puts us another year behind the
- 6 8-ball. That's what's worrying me.
- 7 So I'm trying to figure out now that I've sort of
- 8 moved a little bit off the confidentiality piece -- so just to
- 9 finish the scheduling, I shouldn't get sidetracked. You'll
- 10 tell me in two weeks which way you want to go and the time in
- 11 which you can do it if you want to streamline it or just simply
- 12 say the exhibits are considered incorporated for purposes of
- 13 Igbal/Twombly and other motions, that that would be a way to do
- 14 it. How much after that would -- if they took that route,
- would you be able to file your Iqbal/Twombly motion?
- MR. NOONAN: Well, Your Honor, we don't expect to see
- 17 the consolidated complaint from the states until June 25, so
- 18 that's a problem that we have. So we'd like to have both
- 19 complaints in hand before we move to dismiss.
- THE COURT: I don't understand about the consolidate.
- 21 It's going to be the exact same as the federal complaint or
- it's going to be a separate one?
- 23 MR. NOONAN: It's represented to us that it's quite
- 24 similar, but it's represented to us that the states have
- 25 various Medicaid-specific aspects to it that we will have to

- 1 deal with in some way. We don't think it's going to take as
- 2 much --
- 3 THE COURT: You're all so versed on the federal claim
- 4 that I'd like to get that briefing started, which it will be
- 5 the exact same briefing as the states except with respect to
- 6 state Medicaid fraud statutes. So maybe that -- can the woman
- 7 from the states -- I forget your name?
- 8 MS. PHILLIPS: Lareena Phillips.
- 9 THE COURT: This is helpful, because I'm moving
- 10 forward on this thing. When are you going to be able to file
- 11 your consolidated complaint?
- MS. PHILLIPS: We'll file our consolidation by June
- 13 25. And we do expect it to be very similar to the federal
- 14 complaint. But as you alluded to, we would have our
- 15 state-specific information regarding the various programs.
- 16 THE COURT: Are you content to piggyback on the
- 17 federal complaint with respect to the overarching claims, or
- 18 are there things -- and then just simply brief what's different
- 19 about the state statute?
- MS. PHILLIPS: That is the current plan of the states,
- 21 yes, Your Honor.
- 22 THE COURT: Okay. I'm worried about this because I've
- 23 been down this road before. Are they all different Medicaid
- 24 statutes? Are all they all --
- MS. PHILLIPS: Yes, they would be different Medicaid

- 1 statutes.
- THE COURT: Are they significantly different?
- MS. PHILLIPS: I can't give you that answer right now.
- 4 As I said, I don't expect them to be. I think each state will
- 5 have to do as they need to as their own sovereign, but we do
- 6 expect it to be all very similar.
- 7 THE COURT: Okay, but here's my problem: I'm just me,
- 8 okay? Just me. So if I'm going to be dealing with six
- 9 Iqbal/Twombly motions, that's -- and it's going to go statute
- 10 by statute. I'm assuming there's -- I'm not sure I'll be able
- 11 to get through them all in any kind of meaningful timetable.
- 12 This is such an old case right now. It is so stale. I'm not
- even sure if it's still the pricing scheme. Are you still
- 14 doing this credit card thing?
- 15 MR. NOONAN: Yes, Your Honor. We wouldn't call it a
- 16 pricing scheme, but we are still doing it.
- 17 THE COURT: Pricing approach. How's that?
- 18 MR. NOONAN: The correct price treatment of credit
- 19 card fee payments.
- 20 THE COURT: Okay. Whatever it is, but it's still
- 21 happening so it's not so old. I don't think, though, for
- 22 discovery purposes, I need to go through the nuances of every
- 23 Medicaid statute. I just need to know if there's basically a
- 24 cause of action on the overarching theme. So I think we should
- 25 start the briefing now, and then I will allow you to

- 1 supplement. I can't handle that all on the motions for summary
- 2 judgment -- or motions to dismiss. It will overwhelm me. So
- 3 I'm thinking how long since the federal complaint's been filed
- 4 do you think that you can file your motion to dismiss?
- 5 MR. NOONAN: Well, Your Honor, our only concern is we
- 6 still believe the representations will be very similar, but we
- 7 would like to at least have seen the state's complaints before
- 8 we file.
- 9 THE COURT: I don't want to destroy everyone's July 4;
- 10 everyone should be at the beach or in the mountains.
- MR. NOONAN: Would July 25 be too late to begin, Your
- 12 Honor?
- 13 THE COURT: So let's just assume that the week of July
- 4 is holy, and no associate and no partner should be working
- 15 that week.
- MR. NOONAN: I fully agree.
- 17 THE COURT: No Assistant US Attorney, hardworking,
- 18 nobody from the Department of Justice. It's holy. Nobody
- 19 works. So assuming that we have the week off, what if we were
- 20 to do two weeks after that? Does July 19 destroy anybody's
- 21 summer vacation? No? Okay.
- July 19 will be the motion to dismiss, which is
- 23 limited by our local rules to 20 pages. It's only one claim;
- 24 it's not that hard. You don't need to do two pages on the
- 25 standards of Iqbal/Twombly and 9(b), okay? So I think that

- 1 should about do it. I don't care if there's another couple of
- 2 pages in here, but we're not going to have 50-page motions to
- 3 dismiss.
- 4 MR. NOONAN: We may come back and ask for slightly
- 5 more than 20.
- 6 THE COURT: Slight is doable; big is not. It's not
- 7 that hard a case.
- MR. NOONAN: We agree.
- 9 THE COURT: From the point of view of Iqbal/Twombly --
- 10 I mean, it's a one-issue case, right?
- MR. NOONAN: We also agree.
- 12 THE COURT: And we'll all agree, if that's where the
- 13 Government goes, that they can reference exhibits that are
- 14 referenced in the complaint?
- MR. NOONAN: Yes, Your Honor.
- 16 THE COURT: And from the Government's point of view --
- 17 I'm not here to destroy anybody's time with their children or
- 18 the un-refundable PayPals, that kind of thing. Typically, it's
- 19 21 days, 30 days. What do you want to complete it?
- MS. SEOL: I think -- mindful of the Court's concern
- 21 about delaying the briefing -- it's 60 days given the amount of
- 22 time that Regeneron would have had to put together.
- 23 MR. NOONAN: We have no objection to the Government
- 24 having 60 days to oppose.
- 25 THE COURT: I might. Let me just see this. So that

- 1 puts us into -- you're essentially making this a year hiatus by
- 2 doing that. So, if it's July 19 -- so you want to September 19
- 3 or so?
- 4 MS. SEOL: That's correct, Your Honor.
- 5 THE COURT: And then two weeks for a reply and two
- 6 weeks for a surreply, and I'm expecting from the states only
- 7 one brief if you want to do it, or you can just join in.
- 8 MS. PHILLIPS: I think we would be joining in with the
- 9 federal briefing.
- 10 THE COURT: Yes. Okay, and then I'll deal with your
- 11 separate -- what I'm unlikely to do is spend a lot of time
- 12 right in the beginning on, Well, this subsection on this state
- 13 statute applies, but this subsection of the state statute
- doesn't apply. If there's any cause of action that survives,
- 15 vis-a-vis the Feds, I'm likely to just not hold up discovery
- 16 with the states. We'll just jump right in.
- In the meantime, it's an unusual case because it's a
- 18 False Claims Act case. So I'm assuming you've all done all
- 19 this discovery in terms of documents, right? It's really we're
- 20 going to jump right into depositions; is that right?
- MR. NOONAN: Your Honor, we'd like -- we discussed
- 22 with the states and the Federal Government -- I don't think
- 23 there's any objections -- we'd like there to be no discovery
- 24 until the motions to dismiss are concluded. But you're right,
- 25 there's been three years of document production in this case to

- 1 date.
- THE COURT: From your side.
- 3 MR. NOONAN: Yes, from our side.
- 4 THE COURT: And does the Government have evidence that
- 5 they might not have seen?
- 6 MR. NOONAN: We think there's lots, yes.
- 7 THE COURT: Excuse me?
- 8 MR. NOONAN: We think there's lots of documents that
- 9 we'll ask the Government to put forth.
- 10 THE COURT: Okay. So what I'll try and do is, I'm not
- 11 going to stay discovery if I think -- when I read the motion
- 12 for Iqbal/Twombly -- it's likely to survive. So I'm likely to
- 13 treat the hearing on that also as the scheduling conference,
- 14 and if I think it's likely to survive, I'm going to probably at
- 15 least require you to file joint statements at that time.
- What do you think the discovery should look like?
- 17 MS. SEOL: If I could just say one point. We do
- 18 think, based on our conversations with Regeneron, that there
- 19 may be a potential advice-of-counsel defense. And we think
- 20 that there's a chance that their decision to invoke the
- 21 advice-of- counsel defense or not may --
- THE COURT: Excuse me. For some reason it's getting a
- 23 little foggy. Advice-of-counsel defense?
- MS. SEOL: Right. So based on our discussions with
- 25 Regeneron to date, we think there is a chance that there could

- 1 be an advice-of-counsel defense. So based on whether they
- 2 decide to invoke that defense or not, we think that would have
- 3 a significant impact on the way that the Government conducts
- 4 discovery. So that's something that we have been discussing
- 5 internally and thinking about whether it makes sense to request
- 6 a stay of discovery until Regeneron has decided whether it
- 7 chooses to invoke that defense or not.
- 8 THE COURT: It's a risk you all take by waiting so
- 9 long. It is now a four-year-old case. When was it filed?
- 10 When was the original relator complaint?
- MS. SEOL: I believe it was 2021 now.
- 12 THE CLERK: Judge, it's a 2020 case, though, on your
- 13 docket.
- 14 THE COURT: We're coming into five years. That's not
- 15 good. People's memories -- I'm unlikely to stay discovery if I
- 16 think there's a chance this thing is going forward. Period.
- 17 I'm going to jump right into document exchange. We're going to
- 18 go for it. I've tried AWP; I've tried Neurontin; I've tried
- 19 these cases and I'll try this one if I need to. So I'm not
- 20 afraid of a trial. Been there; done that. I'm terrified about
- 21 what a motion for summary judgment might look like in general.
- 22 The Government probably won't win because they have to prove
- 23 willfulness, but if it's anything like the spread cases I've
- 24 had before, it's often hard for the defense to win on
- 25 willfulness. I don't want this to be another four or five

- 1 years. It doesn't serve the interest of justice.
- What's the role of the relator in this? They are
- 3 basically -- are you there from the relator? Thank you. Is
- 4 there anything that the Government didn't intervene on that's
- 5 sort of lurking in the background?
- 6 MR. BROOKS: There are non-intervene claims, Your
- 7 Honor, but we will not be pursuing them independently.
- 8 THE COURT: Thank you. That's very helpful to hear.
- 9 Let me just ask you this: I'm assuming, because this took so
- 10 long, that there have been settlement discussions; is that
- 11 correct?
- MR. NOONAN: Well, Your Honor, we certainly had many
- 13 meetings with the Government before the Government decided to
- 14 intervene and they did not get anywhere and there have not been
- 15 discussions since then.
- 16 THE COURT: And let me just ask you this. I don't
- 17 know what's been done or whether it's worth it. Is it worth
- 18 trying to come up with a mediation schedule or should we wait
- 19 until after the motion to dismiss is thought about?
- MR. NOONAN: I believe after the motion to dismiss,
- 21 Your Honor.
- THE COURT: So it wasn't as if you were negotiating
- 23 and close and they had to make a decision.
- MR. NOONAN: No.
- 25 THE COURT: So we really do need to sort of roll up

- 1 our sleeves on this and have me look at the case.
- 2 MR. NOONAN: We do, Your Honor.
- 3 THE COURT: I'll make a decision going forward how to
- 4 handle it if the Government doesn't want to follow Plan "A" or
- 5 Plan "B." Now, if they go Plan "B," which is they're going to
- 6 edit out the documents to what they think is essential to their
- 7 case, I'm still stuck with the confidential issue, hopefully
- 8 much reduced. And then what I'm hoping you'll do is confer
- 9 taking into account the age of the case and the sensitivity of
- 10 the information. So I can understand if it's a four- or
- 11 five-year case and it's about distribution fees that that could
- 12 be used against you in negotiating. However, some of the other
- 13 stuff that was discussed I was less swayed by. And then I'll
- 14 have, like, what, 50 things to look at? That's so much easier.
- So just if you could -- you'll decide in two weeks the
- 16 way you want to go. You'll confer on a schedule if it doesn't
- 17 work out, and if it's just that you're going to -- on the
- 18 exhibits, you'll just move forward to briefing as we've just
- 19 set it up, okay? Does that sound good?
- MS. SEOL: Understood, Your Honor.
- THE COURT: Thumb's up?
- MR. NOONAN: Yes, Your Honor.
- 23 THE COURT: Enjoy your summer. Enjoy your July 4
- 24 week, it's an absolute judicial order that no associates or
- 25 attorneys work on this over July 4 week and I think I've given

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you plenty of time where that can happen, okay?
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              MR. NOONAN: Thank you.
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              THE COURT: Enjoy, bye-bye.
             (Whereupon the hearing was adjourned.)
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| 1 | CERTIFICATE OF OFFICIAL REPORTER |
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| 2 | |
| 3 | I, Jessica Leonard, Certified Shorthand Reporter |
| 4 | and Federal Certified Realtime Reporter for the United States |
| 5 | District Court for the District of Massachusetts, do hereby |
| 6 | certify that the foregoing transcript is a true and correct |
| 7 | transcript of the stenographically reported proceedings held in |
| 8 | the above-entitled matter, to the best of my skill and ability. |
| 9 | Dated this 10th day of June, 2024. |
| 10 | |
| 11 | |
| 12 | /s/ Jessica M. Leonard |
| 13 | Jessica M. Leonard, CSR, FCRR |
| 14 | Official Court Reporter |
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